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MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/018,112	PETERSDORF ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-50* is/are pending in the application.

4a) Of the above claim(s) *12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 21-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/26/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19, and 21-50 are pending.
Claims 12-19 are withdrawn.
Claims 1-11 and 21-50 are examined on the merits.

This Office Action is in reply to Applicants' correspondence of 3/26/2007. Claim(s) 20 is/are cancelled; claim(s) 12-19 is/are withdrawn; claim(s) 21-50 has/have been newly added; claim(s) 1-8, 10, 11, and 17 has/have been amended.

Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to put the application in condition for allowance. Any new grounds of rejection presented in this Office Action are necessitated by Applicants' amendments. Any rejections or objections not reiterated herein have been withdrawn in light of the amendments to the claims or as discussed in this Office Action.

This Action is made **FINAL**.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 3/26/2007 prompted the new ground(s) of rejection presented in this Office action (i.e. the application of Guo et al 1994 in the rejection of claims 10 and 11 under 35 USC 103). Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Information Disclosure Statement

1. The IDS of 3/26/2007 has been considered.

Duplicate Claims Warning

2. Applicant is advised that should claims 25-27, 29-31, and 33-37 be found allowable, claims 38-40, 42-44, and 46-50 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

In the instant case, the independent claims 25 and 38 do not differ in the claimed oligonucleotides arrays. Claim 25 is drawn to an array of oligonucleotides that comprise locus polymorphisms of the HLA Class I region, and claim 38 requires that the plurality

of oligonucleotides of the claimed array consists essentially of the same oligonucleotides. However, the transitional phrase 'consisting essentially of' does not serve to differ the array of claim 38 from the array of claim 25 which comprises the same oligonucleotides (see MPEP 2111.03). The various dependent claims that depend from each of the independent claims serve to add the same limitations to each independent claim.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

New Grounds of Rejection
Claim Rejections - 35 USC § 112 2nd – Indefiniteness

The rejections of claims under 35 USC 112 2nd¶ presented in the previous Office Action are withdrawn in light of the amendments to the claims. New grounds of rejection are set forth.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41 and 45 are unclear because they require that particular HLA-B locus polymorphisms are included on the claimed array. However, as the claims are written,

they depend from claims 30 and 26 (which require that the oligonucleotides of the array of claim 25 are HLA-A or HLA-C polymorphisms). As such it is unclear it the arrays of claims 41 and 45 are intended to specifically require the HLA-B polymorphisms as recited in claims 41 and 45 in addition to the particular HLA-C polymorphisms as required by claim 30. Applicant may intend for claim 41 to depend from claim 38.

Claim Rejections - 35 USC § 102
Includes New Rejections

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8, and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (1995, US Patent 5,474,796).

Brennan teaches a microarray that contains 10-mer polynucleotides spotted at discrete locations such that the total array represents every possible permutation of 10-mer oligonucleotide (col. 9, lns. 48-55). The array of Brennan comprises every 10-mer nucleic acid, thus it comprises a plurality of probes sufficient to represent at least 80%, 90%, and 98% of known polymorphisms in the HLA Class I locus, as required by claims 1, 2, and 3, respectively. Because of the comprehensive nature of the 10-mer array of Brennan, the array comprises the HLA-A, HLA-B, and HLA-C polymorphisms as required by claims 6-8, and encompasses any and all polymorphisms of HLA-A,

HLA-B, and HLA-C including the 86 HLA-A polymorphisms required of claim 21, the 185 HLA-B polymorphisms required of claim 22 and the HLA-B exon 2 and 3 polymorphisms of claim 24, and the 45 HLA-C polymorphisms required of claim 23.

Response to Remarks

Applicants have traversed the rejection of claims under 35 USC 102 as anticipated by Brennan. Applicants argue (page 11 of Remarks) that Brennan teaches an enormously broad genus of every 10mer and does not specifically name or describe any particular individual polymorphisms in the HLA Class I locus, and concludes that because Brennan fails to describe HLA Class I polymorphisms, the reference fails to anticipate the claims. The argument has been considered but is not found to be persuasive. The rejected claims have no structural limitations as to what is required for any particular oligonucleotides of an array to be 'HLA Class I oligonucleotide probes' comprising 'polymorphisms in the HLA Class I locus'. There are no sequence limitations or even length limitations for the oligonucleotides of the rejected claims. And while the 10mer array of Brennan is a broad genus of oligonucleotide probes, Applicant has not indicated in any argument, or with any limitations of the claims, how the array of Brennan does not comprises the required oligonucleotide probes that are claimed only as 'HLA Class I oligonucleotide probes' comprising 'polymorphisms in the HLA Class I locus'. Applicant has provided no basis or reasoning as to how the oligonucleotides of the Brennan array fail to satisfy the required limitations of the rejected claims. And while Brennan does not specifically recite the phrase 'HLA Class I locus', the Examiner

maintains that the teaching of a comprehensive array of 10mer oligonucleotides anticipates the broadly claimed oligonucleotide array of the rejected claims.

5. Claims 25, 26, 33, 38, 39, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Apple et al (1995; US Patent 5,451,512).

Apple et al teaches a reverse dot-blot of immobilized probes for the analysis of HLA-A DNA.

Regarding claims 25, 26, 33, 38, 39, and 46, Apple et al teaches an array of oligonucleotide probes that comprise locus polymorphisms of the HLA-A locus including probes that have from 17-23 nucleotides as well as probes that are 20mers (Tables 2A and 2B) and teaches that the probes may be immobilized on a solid support (e.g. col.3 lns.22-25).

6. Claims 25, 27, 28, 38, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Andrien et al (1994; WO 9421818).

Andrien et al teaches a reverse dot-blot of immobilized probes for the analysis of HLA-B DNA.

Regarding claims 25, 27, 28, 38, and 40, Andrien et al teaches an array of oligonucleotide probes that comprise locus polymorphisms of the HLA-B locus including probes that have from 17-23 nucleotides (p.29-30; p.20 last paragraph) and encompass exon 2 (p.6 paragraph 5) and teaches that the probes may be immobilized on a solid support (e.g. p.15 lns.5-10).

Claim Rejections - 35 USC § 103
Includes New Rejections

In the rejection of claims under 35 USC 103, the breadth of the claims is noted. The claimed array does not specifically require any particular probes of specific nucleic acid sequences. The claimed array requires only nucleic acid probes sufficient to represent a particular percentage of known polymorphisms in the HLA Class I locus, where the specification defines a known polymorphism as one that has appeared in the literature or available from a searchable database (page 15 of the instant specification). The claims are thus broadly drawn to an array requiring only probes sufficient to analyze a particular percentage of HLA polymorphisms.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-8, 21-33, and 38-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bettinotti et al (1997) in view of Sapolsky et al (1997, EP 0 785 280 A2).

Bettinotti et al teaches the sequence analysis and typing of HLA-A, B, and C genes from samples of genomic DNA.

Regarding the limitations of claims 1-3, 25, and 38, the reference teaches a database of the sequence of all known HLA-A, B, and C alleles (p.425 – Abstract; p.427, right col., lns.4-12). Thus the database of all known alleles comprises sequence information for HLA Class I region polymorphisms (relevant to claims 25 and 38) including at least 80%, 90%, and 98% of known polymorphisms in the HLA Class I locus, relevant to claims 1, 2, and 3, respectively.

Regarding the limitations of claims 6-8, 26, 27, 28, 39, 40 and 41, the database of Bettinotti et al, which comprise all known HLA-A, B, and C alleles, because of its comprehensive nature, has sequence information pertaining to alleles of HLA-A, B, and C (relevant to claim 6, 26, 27, 39, and 40). Relevant to claims 7, 8, 28 and 41, the reference specifically teaches using the database in a comparison of the sequences of exons 2 and 3 (Fig 1; p.427, right col., lns.4-12) of HLA-A, B, and C.

Regarding the limitations of claims 21-24, 29, 30, 32, and 42-45, the database of Bettinotti et al comprises sequences of at least 86 HLA-A polymorphisms (relevant to claims 21, 29, and 42), at least 185 HLA-B polymorphisms (relevant to claims 22, 31, and 44), at least 45 HLA-C polymorphisms (relevant to claims 23, 30, and 43), and at least 68 exon 2 and 70 exon 3 polymorphisms of HLA-B (relevant to claims 24, 32, and 45).

Bettinotti et al does not teach a microarray of oligonucleotides comprising a plurality of HLA Class I oligonucleotide probes.

Sapolsky et al teach a microarray of oligonucleotides for the detection of polymorphisms. Relevant to arrays of the rejected claims, the reference teaches that an oligonucleotide array may comprise particular oligonucleotide probes complementary to particular polymorphic forms of segments of a nucleic acid sequence (e.g.: p.4. lns.23-29) and probes may encompass one or more polymorphic positions (e.g.: p.4 lns.47-48; Fig 3).

Regarding claims 4 and 5 and the limitations of claims 25 and 38, Sapolsky et al specifically teach that an array for the analysis of polymorphic positions within a given

sequence may be comprised of probes of 20 nucleotides in length (e.g.: Fig. 3; p.8, Example 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created an array of oligonucleotides probes, as taught by Sapolsky et al, using the sequence information of all of the known alleles of HLA-A, B, and C from a database as taught by Bettinotti et al. One would have been motivated to create such an array based on the assertion of Sapolsky et al that methods using such an array allow for the rapid, automatable analysis of polymorphisms (p.1 – Abstract), and the teaching of Bettinotti et al that molecular testing for HLA typing by sequence analysis allows for higher resolution (p.425, left col., last paragraph).

Response to Remarks

Applicants have traversed the rejection of claims under 35 USC 103 as obvious over the teachings of Bettinotti et al in view of Sapolsky et al. Applicants have argued (page 12 of Remarks) that neither Bettinotti et al nor Sapolsky et al teaches or suggests a plurality of oligonucleotides comprising at least 80% of polymorphisms in the HLA Class I locus. The argument has been considered but is not found to be persuasive. Initially it is noted that the limitation that the claim array comprises 'at least 80% of polymorphisms in the HLA Class I locus' is not required for any of claims 25-50. Furthermore, it is noted that the claims do not recite any particular sequence limitations of the oligonucleotide probes of the claimed arrays, with only a limitation of probe length required by claims 4, 5, 9-11, and 25-50). The examiner maintains that Bettinotti et al clearly teaches access to a database of all known HLA-A, B, and C alleles, and that

such a database supplies the information required to created the array of broadly claimed oligonucleotide probes. That Bettinotti et al does not in fact teaches an array of oligonucleotides is resolved by the specific teachings of Sapolsky et al that polymorphic DNA content may be resolved by using any array of oligonucleotide probes. And while Applicants argue that there is no motivation to modify the information regarding the database of all known HLA-A, B, and C alleles of Bettinotti et al with the oligonucleotide arrays of Sapolsky et al, the Examiner maintains that Sapolsky et al clearly asserts that methods using oligonucleotide probes allow for the rapid, automatable analysis of polymorphisms (p.1 – Abstract).

The rejection as set forth is **MAINTAINED**.

8. Claims 9, 34, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bettinotti et al (1997) in view of Sapolsky et al (1997, EP 0 785 280 A2) and further in view of McGall et al (1995 US Patent 5,412,087)

The teachings of Bettinotti et al in view of Sapolsky et al are applied to claims 9, 34, and 47 as they were previously applied to claims 1-8, 21-33, and 38-46.

Bettinotti et al in view of Sapolsky et al do not specifically teach a microarray wherein the solid support is a glass slide.

McGall et al teaches spatially-addressable immobilization of oligonucleotides to create arrays using photolithographic techniques (col.3 lns.35-45). McGall et al specifically teaches arrays wherein the solid support is a glass slide (e.g. Example 1, col.12)

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the glass slide support of McGall et al for the HLA probe array of Bettinotti et al in view of Sapolsky et al. One would have been motivated to do so based on the teachings of McGall et al that such a support can be used for the immobilization of oligonucleotide probes and successful analysis of nucleic acid sequences by hybridization (e.g. Examples 3-6).

Response to Remarks

Applicants have traversed the rejection of claims under 35 USC 103 as obvious over the teachings of Bettinotti et al in view of Sapolsky et al and further in view of McGall et al. Applicants have argued (page 13 of Remarks) that Bettinotti et al in view of Sapolsky et al fails to teach the required limitations of the independent claims. This argument regarding the teachings of Bettinotti et al in view of Sapolsky et al have been addressed previously in this Office Action.

9. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bettinotti et al (1997) in view of Sapolsky et al (1997, EP 0 785 280 A2) and further in view of Lockhart et al (1996 US Patent 5,556,752)

The teachings of Bettinotti et al in view of Sapolsky et al are applied to claims 10 and 11 as they were previously applied to claims 1-8, 21-33, and 38-46.

Bettinotti et al in view of Sapolsky et al do not specifically teach a microarray wherein the surface density is about 250 to about 450 angstom^2/molecule (relevant to claim 10) or about 325 to about 375 angstom^2/molecule (relevant to claim 11).

Lockhart et al teaches microarrays of oligonucleotide probes generated by photolithographic methods (col.12). The reference specifically teaches that oligonucleotides on the array are approximately 100 angstroms apart (col. 22, lns.54-56), which is a surface density of about 250 to about 450 angstom^2/molecule (relevant to claim 10) and about 325 to about 375 angstom^2/molecule (relevant to claim 11).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made the microarray of Bettinotti et al in view of Sapolsky et al with a surface density as taught by Lockhart et al. One would have been motivated to do so based on the assertion of Lockhart et al that such a density allows for the immobilized probes to participate in the formation of a duplex (col. 21, lns.53-55), and the teaching of Sapolsky et al that immobilized probes are useful for the analysis of polymorphisms by a process of hybridization (Example 2).

Response to Remarks

Applicants have traversed the rejection of claims under 35 USC 103 as obvious over the teachings of Bettinotti et al in view of Sapolsky et al and further in view of Lockhart et al. Initially, Applicants have argued (page 14 of Remarks) that Bettinotti et al in view of Sapolsky et al fails to teach the required limitations of the independent claims. This argument regarding the teachings of Bettinotti et al in view of Sapolsky et al have been addressed previously in this Office Action.

Furthermore, Applicants have argued (page 14 of Remarks) that the Examiner has not shown how the probe spacing detailed by Lockhart et al 'teaches the recited

density limitations of Applicants' claims 10 and 11'. This argument has been considered but is not found to be persuasive. Initially it is noted that a measure of the spacing of probes is a measure of probe density (i.e. the spacing of probes provides the number of probes in a given area, where a number per are is a density). Second it is noted that the rejected claims require probe densities of, for example, 'from about 250 to about 450 angstorom^{2}' (emphasis added) where the term 'about' allows for a range of probe densities beyond the specifically recited values and the specification has not indicated any particular densities within the broadly claimed range that are critical to the invention (see for example MPEP 716.02(d) – Demonstration of criticality of a claimed range).

Finally, Applicants have argues (page 14 of remarks), that the type of array of Lockhart et al is qualitatively different from the array examples disclosed in the instant specification. Applicants argue that the probes of the instant invention are not intended to participate in the formation of a duplex as found in Lockhart, where probes for double stranded structures with neighboring probes. However, Applicants have mischaracterized the probe arrays taught by Lockhart et al, where the reference merely indicates that such an inter-probe hybridization is possible, but does not teach that the intended usefulness of the probe density of Lockhart et al is inter-probe hybridization. And while Applicants argue that one skilled in the art would have no motivation to provide an array with the spacing found in Lockhart, the examiner maintains the Lockhart teaches the successful analysis of hybridization of an array with probes at a density within the broadly claimed range, where such a broadly claimed density range is typical of oligonucleotides probes known to those of skill in the art (as evidenced by Guo

et al (1994) p.5459 right col. – Oligonucleotide surface density, structure, and hybridization efficiency, as cited on the IDS of 3/26/2207, the teachings of which art not relied upon for the instant rejection of claims 10 and 11).

10. Claims 10, 11, 35-37 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bettinotti et al (1997) in view of Sapolsky et al (1997, EP 0 785 280 A2) and further in view of Guo et al (1994; as cited on the IDS of 03/26/2007).

The teachings of Bettinotti et al in view of Sapolsky et al are applied to claims 35-37 and 48-50 as they were previously applied to claims 1-8, 21-33, and 38-46.

Bettinotti et al in view of Sapolsky et al does not teach oligonucleotide probes comprising a 15-mer poly-dT linker covalently bound to a solid support.

Guo et al teaches an analysis of parameters for arrays of oligonucleotide probes immobilized on a solid support. Guo et al teaches that oligonucleotides covalently bound to a solid support (Abstract) may be comprised of a hybridization sequence and a spacer with 15 T nucleotides (Figure 1), and further teaches a surface density of probes that is approximately 500 A^2/molecule which satisfies the density limitations of claims 10 and 11.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have the array of Bettinotti et al in view of Sapolsky et al using the oligonucleotide probes structure of Guo et al. One would have been

motivated to use the covalently bound probe structure of Guo et al based on the teachings of Guo et al that such a probe structure allows for efficient probe:target hybridization (p.5459, left col., lns.20-25; p.5460, left col., third paragraph; Figure 3d).

Conclusion

11. No claim is allowable. No claim is free of the teachings of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Stephen Kapushoc
Art Unit 1634

BJ FORMAN, PH.D.
PRIMARY EXAMINER